510(k) Summary for
Dimension Vista™ MALB Flex® reagent cartridge
Dimension Vista™ Protein 3 Calibrator
Dimension Vista™ Protein 3 Control

SEP 19 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K061990

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
D-35001
Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: July 11, 2006

2. Device Name:
Dimension Vista™ Microalbumin Flex® reagent cartridge (MALB)
Dimension Vista™ Protein 3 Calibrator
Dimension Vista™ Protein 3 Control

Classification: Class II; Class II; Class I
Product Code: DCF; JIX; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring N Antiserum to Human Albumin – K860894
Dade Behring N Protein Standard SL – K012470
Dade Behring N/T Protein Control LC – K991704

4. Device Description:

Dimension Vista™ MALB Flex® reagent cartridge
Proteins contained in human urine form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of albumin in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Protein 3 Calibrator
PROT3 CAL is a lyophilized, polygeline based (with urinary proteins of human origin) product containing Albumin.

Dimension Vista™ Protein 3 Control
PROT3 CON is a lyophilized, polygeline and albumin based product containing albumin of human origin.

5. Device Intended Use:

Dimension Vista™ MALB Flex® reagent cartridge:
The MALB method is an *in vitro* diagnostic reagent for the quantitative determination of albumin in human urine on the Dimension Vista™ System. Measurement of Albumin aids in the diagnosis of kidney and intestinal disease.

Dimension Vista™ Protein 3 Calibrator:
Protein 3 Calibrator is an *in vitro* diagnostic product for the calibration of the Microalbumin (MALB) method on the Dimension Vista™ System.

Dimension Vista™ Protein 3 Control:
Protein 3 Control is an assayed intralaboratory quality control for the assessment of precision and analytical bias in determination of Microalbumin (MALB) on the Dimension Vista™ System.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista™ MALB Flex reagent cartridge, Dimension Vista™ Protein 3 Calibrator and Dimension Vista™ Protein 3 Control are substantially equivalent to the Dade Behring N Antiserum to Human Albumin assay (K860894) assay, N Protein Standard SL (K012470) and N/T Protein Control LC (K991704), respectively. The Dimension Vista™ MALB assay, like the Dade Behring N Antiserum to Human Albumin assay is an *in vitro* diagnostic reagent for the quantitative measurement of Microalbumin (MALB) in human urine by means of particle enhanced immunonephelometry.

7. Device Performance Characteristics:

The Dimension Vista™ MALB assay was compared to the Dade Behring N Antiserum to Human Albumin assay on the BN ProSpec® System by evaluating urine samples with concentrations ranging from 5.87 to 332.74 mg/L. Regression analysis of these results yielded the following equation:

Method Comparison Study

	n	Slope	Intercept	Correlation Coefficient
Dimension Vista™ MALB	74	0.988	-0.936	0.996

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 19 2006

Ms. Kathleen Dray-Lyons
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714-6101

Re: k061990
Trade/Device Name: Dimension Vista™ MALB Flex® reagent cartridge
Dimension Vista™ Protein 3 Calibrator
Dimension Vista™ Protein 3 Control
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: DCF, JIT, JJY
Dated: July 11, 2006
Received: July 13, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: **Dimension Vista™ MALB Flex® reagent cartridge**
Dimension Vista™ Protein 3 Calibrator
Dimension Vista™ Protein 3 Control

Indications for Use:

Dimension Vista™ MALB Flex® reagent cartridge:

The MALB method is an *in vitro* diagnostic reagent for the quantitative determination of albumin in human urine on the Dimension Vista™ System. Measurement of albumin aids in the diagnosis of kidney and intestinal disease.

Dimension Vista™ Protein 3 Calibrator:

Protein 3 Calibrator is an *in vitro* diagnostic product for the calibration of the Microalbumin (MALB) method on the Dimension Vista™ System.

Dimension Vista™ Protein 3 Control:

Protein 3 Control is an assayed intralaboratory quality control for the assessment of precision and analytical bias in determination of Microalbumin (MALB) on the Dimension Vista™ System.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K061990